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October 25, 2004

Mr. William C. Maloney
Physicist
Diagnostic Devices Branch (HFZ-322)
Food and Drug Administration
Center for Devices and Radiological Health
2098 Gaither Road
Rockville, MD 20850

Dear Mr. Maloney:

We are in receipt of your letter of October 5, 2004, which states that 3TP's internet website (www.3tp.net)¹ demonstrates that 3TP is marketing its software for intended uses that do not fall within its existing 510(k) clearance.

First, we would like to state that we do not intend to market any of our products for indications beyond the scope of our FDA clearance. Further, in response to your letter 3TP LLC has taken the following actions. We conducted an investigational review of the statements on our website to ensure that all references to the intended use of our software are within the indications of our 510(k) clearance. This review was made in accordance with our previously established 3TP Quality Assurance Manual. All changes on our website necessary to conform to the statements of intended use in our FDA clearance have been implemented within the specified time period indicated in your letter.

To ensure that all future modifications to the website are within the appropriate parameters of the claims specified in our 510(k) clearance, a communication was sent to all relevant employees directing them to review the section of our 3TP Quality Assurance Manual that deals with design and approval of website materials. Also, a copy of the FDA Warning Letter was circulated to employees involved with promotional materials to provide examples of statements that are not acceptable.

We believe these actions are sufficient to rectify the situation, put 3TP in a compliant position regarding our website, and ensure future compliance.

Sincerely,

A handwritten signature in cursive script, appearing to read 'Andreas Muehler', followed by a forward slash and the letter 'S' as a signature mark.

/s/

Andreas Muehler
President
3TP LLC